



This document is scheduled to be published in the Federal Register on 04/02/2015 and available online at <http://federalregister.gov/a/2015-07354>, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0149; FRL-9923-82]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0149, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0149 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0149, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 5, 2014 (79 FR 53009) (FRL-9914-98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8231) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide, difenoconazole in or on pea, and bean, dried shelled, except soybean, subgroup 6C at 0.2 parts per million (ppm); pea, vine at 10 ppm; pea, hay at 40 ppm; and bushberry, subgroup 13–07B at 3.0 ppm. The petition also requested that the existing tolerance for chickpea be removed. That document referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket identified by docket ID number EPA-HQ-OPP-2014-0373, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8209) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR part 180 be amended by increasing existing tolerances for residues of the fungicide, difenoconazole in or on fruit, pome, group 11-10 from 1.0 to 3.0 ppm, and apple, wet pomace from 4.5 to 7.5 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.”

Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”

This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for difenoconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with difenoconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Subchronic and chronic studies with difenoconazole in mice and rats showed decreased body weights, decreased body weight gains and effects on the liver.

In an acute neurotoxicity study in rats, reduced fore-limb grip strength was observed on 1-day in males and clinical signs of neurotoxicity were observed in females at the limit dose of 2,000 milligrams/kilograms (mg/kg). In a subchronic neurotoxicity study in rats, decreased hind limb strength was observed in males only at the mid- and high-doses. However, the effects observed in acute and subchronic neurotoxicity studies are transient, and the dose-response is well characterized with identified no-observed-adverse effects-levels (NOAELs). No systemic toxicity was observed at the limit dose in the most recently submitted 28-day rat dermal toxicity study.

There is no concern for increased qualitative and/or quantitative susceptibility after exposure to difenoconazole in developmental toxicity studies in rats and rabbits, and a reproduction study in rats as fetal/offspring effects occurred in the presence of maternal toxicity. Although there is some evidence that difenoconazole affects antibody levels at doses that cause systemic toxicity, there are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by difenoconazole.

EPA is using the non-linear (reference dose) approach to assess cancer risk. Difenoconazole is not mutagenic, and no evidence of carcinogenicity was seen in rats. Evidence for carcinogenicity was seen in mice (liver tumors), but statistically significant carcinomas tumors were only induced at excessively-high doses. Adenomas (benign tumors) and liver necrosis only were seen at 300 parts per million (ppm) (46 and 58 mg/kg/day in males and females, respectively). Based on excessive toxicity observed at the two highest doses in the study, the presence of only benign tumors and necrosis at the mid-dose, the absence of tumors at the study's lower doses, and the absence of genotoxic effects, EPA has concluded that the chronic point of departure (POD) from the chronic mouse study will be protective of any cancer

effects. The POD from this study is the NOAEL of 30 ppm (4.7 and 5.6 mg/kg/day in males and females, respectively) which was chosen based upon only those biological endpoints which were relevant to tumor development (i.e., hepatocellular hypertrophy, liver necrosis, fatty changes in the liver and bile stasis).

Specific information on the studies received and the nature of the adverse effects caused by difenoconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> on page 44 of the document titled *“Difenoconazole: Human Health Risk Assessment for proposed new foliar uses on legume subgroup 6C and bushberry subgroup 13-07B; post-harvest uses on pome fruit group 11-10; and ornamental plants and vegetable transplants grown in both indoor and outdoor production facilities”* in docket ID number EPA-HQ-OPP-2014-0149.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological POD and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an

occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for difenoconazole used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Difenoconazole for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 25 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day	Acute neurotoxicity study in rats LOAEL= 200 mg/kg in males based on reduced fore-limb grip strength in males on day 1
Chronic dietary (All populations)	NOAEL= 0.96 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day cPAD = 0.01 mg/kg/day	Combined chronic toxicity/carcinogenicity rat; dietary LOAEL = 24.1/32.8 mg/kg/day (M/F) based on cumulative decreases in body-weight gains
Dermal Short-term (1-30 days)	Oral NOAEL = 1.25 mg/kg/day dermal absorption	LOC for MOE = 100	Reproduction and fertility Study rat; dietary Parental/Offspring LOAEL = 12.5 mg/kg/day based on decreased pup weight in

	rate = 6% $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x		males on day 21 and reduction in body-weight gain of F ₀ females prior to mating, gestation and lactation.
Inhalation short-term (1-30 days) Inhalation and oral absorption assumed equivalent	Oral NOAEL = 1.25 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Reproduction and fertility Study rat; dietary Parental/Offspring LOAEL = 12.5 mg/kg/day based on decreased pup weight in males on day 21 and reduction in body-weight gain of F ₀ females prior to mating, gestation and lactation.
Cancer (oral, dermal, inhalation)	The Agency is using a non-linear approach based on the chronic POD to assess the carcinogenic potential of difenoconazole.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to difenoconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing difenoconazole tolerances in 40 CFR 180.475. EPA assessed dietary exposures from difenoconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for difenoconazole. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the United States Department of

Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) information.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA used USDA Pesticide Data Program (PDP) monitoring data, average field trial residues for some commodities, tolerance level residues for the remaining commodities, and average percent crop treated for some commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to difenoconazole. Therefore, a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the chronic dietary exposure analysis, the Agency estimated the PCT for existing uses as follows:

Almond 5%, cabbage 2.5%, cucumbers 5%, garlic 5%, grape 5%, grapefruit 2.5%, onions 5%, orange 2.5%, pecan 2.5%, peach 1%, peppers 2.5%, pistachio 2.5%, pumpkin 2.5%, squash 5%, strawberry 2.5%, sugar beets 15%, tangerine 2.5%, tomatoes 25%, walnut 2.5%, watermelon 5%, and wheat 10%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest

observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which difenoconazole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for difenoconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of difenoconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

The drinking water assessment was performed using a total toxic residue (TTR) method which considers both parent difenoconazole and its major metabolite, CGA- 205375, in surface and groundwater.

Based on the surface water concentration calculator (SWCC) and screening concentration in ground water (SCI-GROW) and pesticide root zone model ground water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) of difenoconazole for acute exposures are estimated to be 20.0 parts per billion (ppb) for surface water and 1.77 ppb for ground water and for chronic exposure assessments are estimated to be 13.6 ppb for surface water and not detected for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 20.0 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Difenoconazole is currently registered for the following uses that could result in residential exposures: Treatment of ornamental plants in commercial and residential landscapes and interior plantscapes. EPA assessed residential exposure using the following assumptions: For residential handlers, adult short-term dermal and inhalation exposure is expected from use on ornamentals (garden/trees). For residential post-application, short-term dermal exposure is expected for both adults and children from post-application activities in treated gardens.

The scenarios used in the aggregate assessment were those that resulted in the highest exposures. The highest exposures consist of the following:

- Short-term dermal exposure to adults from post-application activities in treated gardens, and

- Short-term dermal exposure to children (6-11 years old) from post-application activities in treated gardens.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Difenoconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures

for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Difenoconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including propiconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov>, docket identification (ID) number EPA-HQ-OPP-2005-0497.

The most recent update for the triazoles was conducted on October 24, 2013. The requested new uses of difenoconazole did not significantly change the dietary exposure estimates for free triazole or conjugated triazoles. Therefore, an updated dietary exposure analysis was not conducted. The October 24, 2013 update for triazoles may be found in docket ID number EPA-HQ-OPP-2014-0149.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account

for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The available Agency guideline studies indicated no increased qualitative or quantitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to difenoconazole. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

In a rat developmental toxicity study developmental effects were observed at doses higher than those which caused maternal toxicity. In the rabbit study, developmental effects (increases in post-implantation loss and resorptions and decreases in fetal body weight) were also seen at maternally toxic doses (decreased body weight gain and food consumption). In the 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for difenoconazole is complete.
- ii. There are no clear signs of neurotoxicity following acute, subchronic or chronic dosing in multiple species in the difenoconazole database. The effects observed in acute and subchronic neurotoxicity studies are transient, and the dose-response is well characterized with

identified NOAELs. Based on the toxicity profile, and lack of concern for neurotoxicity, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that difenoconazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary risk assessment is conservative, using tolerance level residues and 100 PCT for the acute assessment while the chronic assessment used USDA PDP monitoring data, average field trial residues for some commodities, tolerance level residues for remaining commodities, and average PCT for some commodities. These assumptions will not underestimate dietary exposure to difenoconazole. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to difenoconazole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by difenoconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to difenoconazole will occupy 49% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to difenoconazole from food and water will utilize 88% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of difenoconazole is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Difenoconazole is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to difenoconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 170 for adults and 190 for children. Because EPA's level of concern for difenoconazole is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, difenoconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment

of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for difenoconazole.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A, the chronic dietary risk assessment is protective of any potential cancer effects. Based on the results of that assessment, EPA concludes that difenoconazole is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to difenoconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method, GC/NPD method AG-575B, is available for the determination of residues of difenoconazole *per se* in/on plant commodities. An adequate enforcement method, liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method REM 147.07b, is available for the determination of residues of difenoconazole and CGA-205375 in livestock commodities. Adequate confirmatory methods are also available.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FDCA section

408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has an established MRL for the sum of difenoconazole and its metabolite, 1-[2-chloro-4-(4-chlorophenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethano), expressed as difenoconazole in or on milk at 0.02 ppm, which is the same as the recommended U.S. tolerance.

The Codex has not established an MRL for difenoconazole in or on pea and bean, dried shelled, except soybean, subgroup 6C; bushberry subgroup 13-07B; pea, field, hay; pea, field, vines; or apple, wet pomace.

The Codex has an established MRL for difenoconazole in or on pome fruit at 0.5 ppm for residues incurred from foliar uses of difenoconazole. This MRL differs from the recommended U.S. tolerance for difenoconazole in or on fruit, pome, group 11-10 at 5.0 ppm. The Codex MRL is not adequate to cover residues incurred from the proposed post-harvest uses in the United States; therefore, harmonization with Codex is not possible at this time.

C. Response to Comments

Several comments were received in response to the notice of filing, however, all were concerned with effects to bees and related to other petitions and chemicals contained in the same notice of filing, not difenoconazole.

D. Revisions to Petitioned-For Tolerances

The tolerance being established for the bushberry subgroup 13-07B is 4.0 ppm, not 3.0 ppm as proposed. This is due to the independent field trial determination which resulted in the exclusion of one of the trials from the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. The tolerance being established for the pea and bean, dried shelled, except soybean, subgroup 6C tolerance is being set at 0.20 ppm, not 0.2 ppm, and is based on the current practice of setting tolerances to 2 significant figures. The established tolerance in milk is being increased from 0.01 ppm to 0.02 ppm because of the new pea hay and vine feedstuffs which significantly increased the maximum reasonably balanced dietary estimate for dairy cattle. Furthermore, the Agency is establishing tolerances for the fruit, pome, group 11-10 and apple, wet pomace (5.0 ppm and 25 ppm, respectively) at higher levels than requested (3.0 ppm and 7.5 ppm, respectively). The established tolerances for fruit, pome, group 11-10 take into account maximum tolerance estimates that may result from post-harvest application techniques for pome fruit. The established tolerances for apple, wet pomace was calculated based on the highest average field trial residues in or on apples and the average processing factor for wet pomace. Lastly, some commodity terms were modified to be consistent with Agency's preferred food and feed commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of difenoconazole, in or on bushberry subgroup 13-07B at 4.0 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.20 ppm; pea, field, hay at 40 ppm; and pea, field, vines at 10 ppm. Additionally, existing tolerances are modified as follows: apple, wet pomace from 7.5 ppm to 25 ppm; fruit, pome, group 11-10 from 3.0 to 5.0 ppm; and milk from 0.01 to 0.02 ppm. Lastly, the existing chickpea tolerance is

removed as unnecessary since it is now covered by the pea and bean, dried shelled, except soybean, subgroup 6C tolerance.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government

and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 25, 2015

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.475:

i. Remove “Chickpea” from the table in paragraph (a)(1).

ii. Add alphabetically the entries for “Bushberry subgroup 13-07B”, “Pea and bean, dried shelled, except soybean, subgroup 6C”, “Pea, field, hay”, and “Pea, field, vines” to the table in paragraph (a)(1).

iii. Revise the entries for “Apple, wet pomace” and “Fruit, pome, group 11-10” in the table in paragraph (a)(1).

iv. Revise the entry for “Milk” in the table in paragraph (a)(2).

The amendments read as follows:

§ 180.475 Difenconazole; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
* * *	* * *
Apple, wet pomace	25
* * *	* * *
Bushberry subgroup 13-07B	4.0
* * *	* * *
Fruit, pome, group 11-10	5.0
* * *	* * *
Pea and bean, dried shelled, except soybean, subgroup 6C	0.20
Pea, field, hay	40
Pea, field, vines	10
* * *	* * *

(2) * * *

Commodity	Parts per million
* *	* * *
Milk	0.02
* *	* * *

* * * *

[FR Doc. 2015-07354 Filed: 4/1/2015 08:45 am; Publication Date: 4/2/2015]